SUPPORTING STATEMENT

Part A

Making It Easier for Patients to Understand Health Information and Navigate Health Care Systems:

Developing Quality Improvement Measures

March 14, 2016

Agency of Healthcare Research and Quality (AHRQ)

Table of contents

A. Justification

1. Circumstances that Make the Collection of Information Necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ), set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care;

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ conducts and supports research, evaluations, and demonstration projects, with respect to (A) the delivery of health care in inner-city areas and in rural areas (including frontier areas); and (B) health care for priority populations, which includes (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

A goal of Healthy People 2020 is to increase Americans' health literacy, defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." [1] The effects of limited health literacy are numerous and serious, including medication non-adherence resulting from patients' inability to read and comprehend medication labels; underuse of preventive measures, such as vaccines; poor self-management of conditions such as asthma and diabetes; and higher utilization of inpatient and emergency department care. [2,3] According to the 2003 National Assessment of Adult Literacy, 88% of US adults have significant difficulties understanding widely used health information. [4] By adopting "health literacy universal precautions," health care providers and organizations can create an environment in which all patients – regardless of health literacy level – can successfully (1) understand health information, (2) navigate the health care system, (3) engage in medical decision-making, and (4) manage their health.

Numerous resources have been developed to support health care organizations in their attempts to address limitations in patient health literacy. [5] However, little work has been done to establish valid quality improvement measures that organizations can use to monitor the impact of initiatives aimed at improving patient understanding, navigation,

engagement, and self-management. Absent such measures, organizations may be unable to accurately assess whether their initiatives are effective.

This research has the following goals:

1. Identify existing quality improvement measures and gather proposals for additional measures (not generated from patient survey data) that organizations may use to monitor progress related to enhancing patient understanding, navigation, engagement, and self-management; and

2. Identify a set of quality improvement measures that reflects patient priorities, has expert support, and can be recommended for more formal measure development and testing.

To achieve the goals of this project, AHRQ's contractor, the Board of Regents of the University of Colorado, has designed a Measurement Identification and Validation Plan that includes the following activities and data collections.

1. **Assemble a Technical Expert Panel**: A panel of 9 experts with health care industry experience was convened and provided feedback on critical measurement topics, including: (1) the conceptual framework that will serve as the foundation for all project work; (2) existing quality measures that can be used to monitor quality improvement initiatives aimed at enhancing patient understanding, navigation, engagement, and self-management; (3) suggested additional measures that might be of value; (4) the criteria by which measures should be evaluated; and (5) organizations engaged in relevant quality improvement activities. This activity does not impose a burden on the public, does not require OMB clearance, and is not included in the burden estimates in Section 12.

2. **Conduct a Literature Review:** Building upon prior efforts to identify resources and data collection tools designed to guide organizations in their health literacy-related quality improvement efforts, a review of the peer-reviewed and grey literatures will be conducted to identify quality improvement measures that organizations can use to monitor the outcomes of such initiatives. This activity does not impose a burden on the public, does not require OMB clearance, and is not included in the burden estimates in Section 12.

3. **Issue a Request for Information**: AHRQ has published a Request for Information (RFI) in the Federal Register. The RFI will provide background information on the project and request recommendations from the public for quality improvement measures that can be used to monitor the impact of activities aimed at improving patient understanding, navigation, engagement, and self-management (and that can be computed without the use of patient survey data). To ensure that individuals with relevant expertise are alerted to the RFI, AHRQ will post information about it on a robust health literacy listserv managed by the Institute for Healthcare Advancement and through AHRQ's GovDelivery list of 64,000 subscribers of health literacy and cultural competence updates.

Responders will be asked to provide as much detail as possible about each recommended measure. Twenty individuals are expected to respond to the RFI. This activity does not impose a burden on the public, does not require OMB clearance, and is not included in the burden estimates in Section 12.

4. **Conduct Patient Focus Groups**: Two Patient Focus Groups, consisting of 4 or 5 patients each with a total of no more than 9 patients across both groups, will provide input on activities health care organizations can do to enhance patient understanding, navigation, engagement, and self-management. Patients will be recruited from two health systems serving low-income patients. One of the Patient Focus Groups will be conducted in English and the other in Spanish. This data collection activity involves only 9 individuals, does not require OMB clearance, and is not included in the burden estimates in Section 12.

   Environmental Scan Interviews: Representatives from 25 health care organizations engaged in relevant quality improvement efforts will be interviewed to obtain information about the quality improvement measures they use in assessing their work to improve patient understanding, navigation, engagement, and self-care (see Attachment A). This is the only data collection that requires OMB clearance. Burden estimates in Section 12 are based on this activity.

5. **Delphi Panel Review of Measures**: A modified Delphi process, known as the RAND/UCLA Appropriateness Method, will be used to establish face validity and examine other characteristics of identified quality measures. A panel of 9 to 12 expert and stakeholder consultants will independently review and rate a set of measures on two occasions and will participate in a 3 to 4 hour Webinar in between rounds of rating to discuss areas of disagreement among raters. This activity does not impose a burden on the public, does not require OMB clearance, and is not included in the burden estimates in Section 12.

This project is being conducted by AHRQ through its contractor, Board of Regents of the University of Colorado, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

Health care organizations have only recently taken responsibility for making health information easier to understand and systems easier to navigate, and for engaging patients and giving them support to manage their health. Published reports lag behind progress made by pioneering health care organizations that are attempting to reduce the demands made on patients. Only through interviews with representatives of organizations that are leading the field will we be able to capture the state of the art in this measurement area.

The planned environmental scan interviews will provide the information needed to:

- identify and document the characteristics of relevant quality improvement measures that are already in use; and

- identify additional measures that would be useful to stakeholders in the field.

The findings from these interviews will be used, along with the results from other activities described in Section 1, to identify and document a set of quality improvement measures that can be recommended for rigorous testing and validation. Measures that prove to be valid and reliable are eligible to be disseminated by AHRQ to support health care organizations in their efforts to improve patient understanding of health information, navigation of the health care system, engagement in medical decision-making, and management of their health.

3. Use of Improved Information Technology

A health literacy listserv and AHRQ's health literacy and cultural competence GovDelivery mechanism will be used in the process of identifying candidates for the Environmental Scan Interviews. Teleconferencing technology will be used to conduct and record the interviews for transcription and analysis. Screen-sharing technology will be used to facilitate sharing of information with interview participants who consent to use of this technology.

4. Efforts to Identify Duplication

This project will build upon – but not duplicate – other efforts in this area. These include:

- An Institute of Medicine (IOM)-commissioned review of the literature that identified numerous self-assessment and patient-reported data collection tools that organizations can use to guide quality improvement initiatives aimed at enhancing patient understanding, navigation, engagement, and self-management.[5] The review did not, however, identify quality improvement measures that can be used to monitor the impact of these efforts. Therefore, the proposed project excludes self-assessment and patient-reported, and instead focuses on operational measures.
- An Institute of Medicine (IOM)-commissioned scan of health literacy efforts in the United States.[6]
- An Institute of Medicine (IOM) workshop on implementation of organizational health literacy.[7]

Through the publication of the RFI in the Federal Register and the use of listserv and GovDelivery mechanisms, AHRQ will uncover any other work that is currently being conducted in this area and ensure that duplication is avoided.

5. Involvement of Small Entities

Although most of the health care organizations that participate in the Environmental Scan Interviews will not be small entities, our purposive sampling will include one or two small entities. The same information will be requested from all selected organizational

respondents, but smaller entities are likely to have fewer initiatives and measures to report on and thus the reporting burden is expected to be smaller. The information being requested from all respondents is the minimum required to achieve the project objectives.

6. Consequences if Information Collected Less Frequently

This is a one-time data collection.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a.   Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on *February 10, 2016, on Page 7118 / Vol. 81, No. 27* for 60 days (see Attachment B). No substantive comments were received.

8.b.   Consultation Outside the Agency

To ensure the perspectives of diverse stakeholders are represented, the project has enlisted a Technical Expert Panel to advise it. Similarly, the project will use a Delphi Panel to aid in selection of the final set of measures recommended for further testing.

All TEP members were representatives of health care and/or consulting organizations and had expertise related to quality improvement initiatives aimed at improving patient understanding, navigation, engagement, and self-management. Exhibit 1 identifies the panel members and describes their background and experience.

Exhibit 1. Technical Expert Panel Membership

Member	Background
Mary Ann Abrams, MD, MPH	Physician in Ambulatory Pediatrics with Nationwide Children's; Iowa state health literacy coalition; American Academy of Pediatrics Health Literacy Project Advisory Committee and the American College of Physicians Foundation Health Literacy Programs Committee.
Tom Bauer, MBA	Corporate Director, Remarkable Patient Experience, Novant Health, leading implementation of health literacy-focused interventions, including efforts to improve patient education and communication, refining medical records systems, and addressing patient safety.
Karen Jones, MD	Senior Vice President, WellSpan Health; President, WellSpan Medical Group; Physician Champion to the RWJF-funded Aligning Forces for Quality project in South Central Pennsylvania, which brings providers, consumers and payers together to improve quality of care, publicly report data, and change how care is paid for.
Karen Komondor, RN, BSN, CCRN	Director of Organizational Development, Health Literacy Institute, St. Vincent Charity Medical Center, leading organization's initiative to address health literacy; Invited speaker at IOM workshop "Implementation of Attributes of Health Literacy."

Member	Background
Laura Noonan, MD	Director, Center for Advancing Pediatric Excellence, a quality improvement training program at Levine Children's Hospital;[8,9] Collaborative Director for Carolinas HealthCare System's health literacy quality improvement initiative; Invited speaker at IOM workshop on organizational health literacy.
Terri Ann Parnell, DNP, RN	Formerly Vice President, Health Literacy and Patient Education, North Shore-LIJ Health System, where she oversaw organizational health literacy quality improvement efforts across health system; Director, Health Literacy Partners, a firm supporting organizations in their efforts to become more health literate; Invited speaker at IOM workshop and lead author on IOM discussion paper on organizational health literacy.[10]
Jennifer Pearce, MPA	Health Literacy Program Manager at Sutter Health, which has implemented multiple tactics to address organizational health literacy, including making changes in staffing and organizational policies as well as conducting training and implementing strategies for clear communication. Jennifer also has a strong patient engagement background.
Audrey Riffenburgh, MA	Formerly Senior Health Literacy Specialist overseeing system-wide organizational health literacy interventions in the University of New Mexico Hospitals, which included a focus on leadership, staffing, organizational self-assessment, communication, and navigation assistance; Co-author of Building Health Literate Organizations: A Guidebook to Achieving Organizational Change;[11] President, Plain Language Works, a firm specializing in guiding organizations in becoming more health literate; Invited speaker at IOM workshop on organizational health literacy.
Ulfat Shaikh, MD, MPH	Director for Health Care Quality and Associate Professor of Pediatrics, University of California Davis; Quality Improvement Project Leader for the American Academy of Pediatrics (AAP) Council on Quality Improvement and Patient Safety; previously served as the Clinical Quality Officer for the California Department of Health Care Services. In her work with the AAP, she is working to improve care of children and adolescents through implementation of health literacy best practices in clinical settings.

To ensure that a diverse array of perspectives is obtained from the Delphi panel, members will include individuals with expertise in (1) barriers to patient understanding, navigation, engagement, and self-management; (2) quality measure development and evaluation; (3) implementation of quality improvement initiatives aimed at enhancing patient understanding, navigation, engagement, and self-management; and (4) the patient and/or caregiver perspective. The Delphi panel will include several members of the Technical Expert Panel and add new members to increase expertise related to development and evaluation of quality improvement measures and to gain new perspectives.

Dr. Debra Saliba, MD, MPH, AGSF [Class I], also will serve as a consultant for the project. Dr. Saliba is Professor and holder of the Anna & Harry Borun Endowed Chair in Geriatrics at the University of California Los Angeles (UCLA). She directs the UCLA Borun Center for Gerontological Research and is a physician researcher with the Los Angeles Veterans Affairs Medical Center. As a practicing geriatrician and well-published health services researcher, she has 20 years of experience in developing and evaluating measures of health care quality. She has particular expertise in using consensus development methods, such as the modified Delphi methodology that will be use on this project to identify and validate quality measures. During Project Year 1, Dr. Saliba will provide guidance on identification and documentation of existing quality

measures. In Project Year 2, she will collaborate with the project team to finalize methods and materials for the Delphi Panel review, will moderate the panel meeting, and work with the team to analyze and synthesize the results.

9. Payments/Gifts to Respondents

Organization representatives who respond to the Environmental Scan Interviews will not receive any payment or gift for their participation.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act 42 U.S.C. 299c-3(c). That law requires that information collected in AHRQ-supported research that identifies individuals or establishments be used only for the purpose for which it was supplied.

All research activities will be reviewed by the Colorado Multiple Institutional Review Board (COMIRB), the Institutional Review Board (IRB) that oversees research conducted at the University of Colorado Anschutz Medical Campus. COMIRB's Federal-wide Assurance (FWA) with the Office for Human Research Protections of the U.S. Department of Health and Human Services provides that the organization will assure compliance with the Terms of Assurance for Federally-supported research. The research team will submit all data collection protocols to COMIRB for review and approval and will follow COMIRB-approved procedures for obtaining participant consent. The team will follow procedures outlined in the AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. As project-related data collection activities (e.g., Patient Focus Groups) present minimal risk of harm to participants, we do not anticipate challenges in obtaining IRB approval.

Information that can directly identify the Patient Focus Group participants, such as name and/or social security number will not be collected. Written information that can directly identify the organizations responding to the Environmental Scan Interviews will only include organization's name and location. The name and title of participants in the Environmental Scan Interviews will be recorded.

Although findings may be disseminated in written reports or presentations, identifying information about Patient Focus Group participants will not be collected or reported. All hardcopy data (e.g., Patient Information Forms) will be stored in a locked filing cabinet located in a secure, limited-access setting accessible only to the project team. All electronic data (e.g., interview transcripts) will be stored in an access-controlled directory on a secure server at the University of Colorado Anschutz Medical Campus. Only project staff will have access to the project directory.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature. The Participant Information Form, which will be completed by participants during the Patient Focus Groups, comprises eight questions intended to ascertain age, gender, race/ethnicity, educational attainment,

employment status, and reading ability. The consent process will include a statement that participants may skip any question they do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 2 shows the estimated annualized burden hours for the respondents' time to participate in Environmental Scan Interviews. An average of two respondents for each of the 25 organizations will participate in the Environmental Scan Interviews for a total of 50 respondents.

Exhibit 3 shows the estimated annual cost burden associated with the respondents' time to participate in this information collection. The annual cost burden for the Environmental Scan Interviews is estimated to be $4,984.

Exhibit 2. Estimated Annualized Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours
Environmental Scan Interviews	50	1	2	100
Total	50	1	2	100

Exhibit 3. Estimated Annualized Cost Burden

Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate*	Total Cost Burden
Environmental Scan Interviews	50	100	$49.84[a]	$4,984
Total	50	100	$49.84[a]	$4,984

* National Compensation Survey: Occupational wages in the United States May 2014, "U.S. Department of Labor, Bureau of Labor Statistics."

[a] Based on the mean wages for Medical and Health Services Managers 11-9111

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the project.

14. Estimates of Annualized Cost to the Government

Exhibit 4 shows the total and annualized cost for the data collection activities. The total cost to the government of the data collection activities is $68,211over a 22-month period; hence, the annualized cost is $37,206. These costs will be incurred from September 2015 through July 2017.

Exhibit 4. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$10,529	$5,743
Data Collection Activities	$15,633	$8,527
Data Processing and Analysis	$7,894	$4,306
Publication of Results	$5,378	$2,933
Project Management	$2,901	$1,582
Overhead	$25,876	$14,114
Total	$68,211	$37,206

Exhibit 5 shows the annual cost to AHRQ of overseeing this data collection.

Exhibit 5: Annual Cost to AHRQ for Contract Oversight

Tasks/Personnel	Staff Count	Annual Salary	% of Time	Cost
Management and Research Support: GS-15, Step 10 average	1	$160,300	1.5%	$2,405
Grand Total				$2,405

Annual salaries based on 2016 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf

Note that these oversight costs are included in "Overhead" in Exhibit 4.

15. Changes in Hour Burden

This is a new data collection effort and does not build on a previous submission.

16. Time Schedule, Publication and Analysis Plans

16.a. Time Schedule

Timing of project-related activities is presented in Exhibit 4. The timing of the Environmental Scan Interviews is dependent on receipt of OMB clearance, which we expect to receive by July 21, 2016. Assuming that clearance is received by that date, the following schedule of project activities will be followed:

Exhibit 6. Project Timeline

Task	Start Date	End Date
Develop Measurement Identification and Validation Plan	9/21/15	11/16/2015
Recruit panel members and conduct Technical Expert Panel meeting	9/21/2015	12/18/2015
Publish Request for Information	11/27/2015	2/25/2016
Obtain IRB approval	2/12/2016	3/24/2016
Recruit patients and conduct Patient Focus Groups	5/9/2016	6/17/2016
Submit IRB amendment if changes are needed based on OMB review	7/21/2016	7/21/2016
Recruit organizations and conduct Environmental Scan Interviews	7/22/2016	10/20/2016
Prepare report summarizing results of measure identification activities	9/12/2016	12/12/2016
Recruit panel members and conduct Delphi Panel Review of Measures	9/21/2016	3/16/2017
Prepare report summarizing results of Delphi Panel Review of Measures	3/17/2017	5/11/2017
Prepare Final Report	4/14/2017	6/30/2017
Prepare manuscript for publication in peer-reviewed journal	4/10/2017	7/7/2017

16.b. Publication and Use of Findings

AHRQ plans to submit at least one manuscript describing project findings to a peer-reviewed journal.

16.c. Analysis Plans

The objective of this project is to identify and evaluate quality improvement measures that may be useful in monitoring the impact of initiatives aimed at enhancing patient understanding, navigation, engagement, and self-management. The project is intended to be an exploratory project representing the first phase of a larger process to develop valid and reliable quality improvement measures for use by health care organizations doing such quality improvement work. Multiple methods will be used to ensure a wide array of measures are identified and evaluated as part of the project, with the intention to produce a candidate set of measures that can be further developed and tested, including rigorous psychometric testing.

Both qualitative and quantitative data will be collected as part of the study. Qualitative data will be collected as part of the Technical Expert Panel meeting, Patient Focus Groups, and Environmental Scan Interviews. Each of these discussions/interviews will be recorded and transcribed verbatim. Consistent with established qualitative methodology, all qualitative analyses will involve a continuous, iterative process beginning with initial data collection and continuing throughout and beyond the data coding and analysis activities. After initial codes are established, the resulting code set will be applied to all transcripts and code categories using an emergent rather than an a priori analysis approach. [12,13]

Qualitative analyses will be used to (1) identify needed refinements to the conceptual framework underlying all project work (Technical Expert Panel), (2) finalize the criteria by which measures will be evaluated during the project (Technical Expert Panel), (3) identify and assess the potential value of specific measures (Technical Expert Panel, Environmental Scan Interviews, Delphi Panel Review of Measures), (4) identify key themes related to organizations' practical experiences in monitoring their relevant quality improvement activities, including facilitators of and barriers to effective monitoring (Environmental Scan Interviews), and (5) identify patient priorities with regard to

changes organizations can make to address patient understanding, navigation, engagement, and self-management (Patient Focus Groups, Delphi Panel Review of Measures).

Quantitative data will be collected as part of the Patient Focus Groups and the Delphi Panel Review of Measures. Following completion of the Patient Focus Groups, descriptive analyses (e.g., mean, frequency distributions) of data collected in the Participant Information Form will be used to describe the participant sample. During the Delphi Panel Review of Measures, participants will independently rate each measure on several criteria (e.g., face validity, feasibility). Following each round of review, the ratings will be analyzed by computing the frequency distribution and median for each criterion for each measure. After the first round, results will be synthesized. The panelists will receive quantitative results for each measure, a summary of written comments, and a list of any new measures proposed during the first round of review. Following the panel meeting, at which disagreements among the panelists will be discussed, each member will rerate all measures. Descriptive analyses (e.g., mean, frequency distributions) will again be computed and used to identify measures perceived to be of clear value as well as measures of more moderate or limited value. In identifying measures to be worthy of further study, the same analytic procedures employed in developing the AHRQ Quality Indicators will be used. [14]

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A -- Environmental Scan Semi-Structured Interview Guide

Attachment B -- Federal Register Notice

References

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